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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/366,081 08/02/99 BRENNER

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EXAMINER

HM12/0425

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ART UNIT

PAPER NUMBER

1635

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File copy

Office Action SummaryApplication No.
09/366,081

Applicant(s)

BRENNER

Examiner

Mark L. Shibuya

Group Art Unit

1635☒ Responsive to communication(s) filed on Aug 2, 1999☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☒ Claim(s) 1-13 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2☐ Interview Summary, PTO-413☒ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Reissue Applications

1. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.
2. Claims 1-13 are rejected under 35 U.S.C. 251 as being improperly broadened in a reissue application made and sworn to by the assignee and not the patentee. The polynucleotides of claim 5 are broader in scope than the oligonucleotide tag complements comprising a plurality of subunits selected from a minimally cross-hybridizing set, as claimed in claims 1-4 of U.S. Pat. No. 5,654,413 (the patent that applicants seek to reissue in the instant application).

Request to Use Computer Readable Form from Another Application

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because no computer readable form has been entered.
4. The following paragraph, or language having the same effect, can be used to invoke the procedures of 37 CFR section 1.821(e) in which an identical computer readable form from another application is used in a given application. The paragraph should be incorporated into a separate paper to be submitted in the given application:

The computer readable form in this application, 08/1000,000, is identical with that filed in Application Number 07/999,999, filed March 1, 1998. In accordance with 37 CFR 1.821(e), please use the [first-filed, last-filed or

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only, whichever is applicable] computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the Sequence Listing is [included in the originally-filed specification of the instant application, amendment for incorporation into the specification, whichever is applicable].

The sequence listing of the instant application appears to be the same as that filed for 08/484,712, application filed June 5, 1995, now U.S. Patent No. 5,654,413, of which the instant application is a reissue application.

Information Disclosure Statement

5. All references cited in the original patent must be cited again in the reissue. Note that PCT publications should be cited by patent number only under Foreign Patent Documents.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 5, 7, and 9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 73, 77, and 78 of copending

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Application No. 09/092,226. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compositions comprising a mixture of microparticles, each microparticle comprising polynucleotides of a population attached thereto such that substantially all different polynucleotides in the population are attached to different microparticles, wherein the polynucleotide is cDNA, and wherein microparticles comprise tag complements and cDNAs that contain an oligonucleotide tag such that perfectly matched duplexes are formed between the tag complements and the tags of the cDNA, as claimed in claims 5, 7, and 9 of the instant application, encompass and are obvious over the compositions comprising a mixture of microparticles, each microparticle comprising polynucleotides of a population attached thereto such that substantially all different polynucleotides in the population are attached to different microparticles and wherein the population is a cDNA library or a library of genomic DNA fragments, wherein the polynucleotide is cDNA, and wherein microparticles comprise tag complements and cDNAs that contain an oligonucleotide tag such that perfectly matched duplexes are formed between the tag complements and the tags of the cDNA, as claimed in claims 73, 77, and 78 of copending Application No. 09/092,226.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 46-52 of copending Application No.

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09/183,650. Although the conflicting claims are not identical, they are not patentably distinct from each other because genus claims 1-4 of the instant application, drawn to compositions comprising a solid phase support having one or more spatially discrete regions; and a uniform population of substantially identical tag complements covalently attached to the solid phase support in at least one of the one or more spatially discrete regions, the tag complements each comprising a plurality of subunits, each subunit consisting of an oligomer having a length of from three to six monomers and each subunit being selected from a minimally cross-hybridizing set and wherein said microparticle is made of glass, polystyrene, nylon, cellulose, dextran, latex, polyacrolein, or acrylic copolymer, encompass and are obvious over narrower claims 46-52 of copending Application No. 09/183,650, drawn to compositions comprising a solid phase support having one or more spatially discrete regions; and a uniform population of substantially identical tag complements covalently attached to the solid phase support in at least one of the one or more spatially discrete regions, the tag complements each comprising a plurality of subunits, each subunit consisting of an oligomer having a length of from three to six monomers and each subunit being selected from a minimally cross-hybridizing set, wherein each of the monomers is selected from a group consisting of nucleoside N3'→P5' phosphoramidates and peptide nucleic acids, wherein the tag complements have a length in the range from 10-40 monomers and the solid support is a microparticle having a single spatially discrete region, wherein said microparticle is made of glass, polystyrene, nylon, cellulose, dextran, latex, polyacrolein, or acrylic copolymer;

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wherein the tag complements have a length in the range from 12-30 monomers and the solid support is a microparticle having a single spatially discrete region.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 U.S.C. § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 8 recites the language "said population of said cDNAs has a size of from ten to a hundred thousand", which renders the claim indefinite, because the term "size" is capable of more than one meaning in the context of the claim. The "size" of the population may refer to the total number of molecules of cDNAs, regardless of sequence, or "size" may refer to the number of different kinds (sequences) of cDNAs, *i.e.*, the size of the repertory (complexity) of the population of cDNAs.

Claim Rejections - 35 U.S.C. § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Dower et al., WO 93/06121 (applicant's reference).

a. Dower et al., WO 93/0612, at p. 6, line 5, p. 8, lines 18-21, p. 9, lines 1-15, p. 11, lines 6-14 and lines 24-p. 12, line 33, p. 13, lines 22-23, p. 14, lines 19-27, p. 21, lines 5-17 and p. 32, line 22-33, line 7, Example 1, and Figures 1 and 2 disclose compositions comprising a mixture of microparticles, each microparticle comprising polynucleotides of a population attached thereto such that substantially all different polynucleotides in the population are attached to different microparticles.

Claim Rejections - 35 U.S.C. § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dower et al., WO 93/06121, as applied to claim 5 above, and further in view of Chetverin et al., WO 93/17126. The claimed invention is interpreted in view of the rejection of claim 8 under 35 U.S.C. 112, second paragraph (discussed above in the instant office action).

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a. **Dower et al., WO 93/0612**, at p. 5, lines 6-9, p. 8, lines 18-21, p. 9, lines 1-15, p. 11, lines 6-14 and lines 24-p. 12, line 33, p. 13, lines 22-23, p. 14, lines 19-27, p. 21, lines 5-17 and p. 32, line 22-33, line 7, Example 1, and Figures 1 and 2 disclose compositions comprising a mixture of microparticles, each microparticle comprising polynucleotides of a population attached thereto such that substantially all different polynucleotides in the population are attached to different microparticles and wherein the microparticles are of sizes appropriate for specific screening strategies (e.g., fluorescence-activated cell sorters [FACS]).

b. Dower et al., WO 93/06121 (applicant's reference) does not disclose microparticles with attached populations of polynucleotides that are populations of cDNAs and microparticles comprising tag complements and cDNAs that contain an oligonucleotide tag such that perfectly matched duplexes are formed between the tag complements and the tags of the cDNA.

c. **Chetverin et al., WO 93/17126 (applicant's reference)**, at p. 35, para 2-3, teach polynucleotides that are cDNAs that are reverse transcribed from mRNA, wherein said cDNAs contain an oligonucleotide tag such that perfectly matched duplexes are formed between the tag complements and the tags of the cDNA.

d. It would have been *prima facie* obvious at the time the invention was made for one of ordinary skill in the art to have made and used microparticles comprising cDNAs, wherein said cDNAs contain oligonucleotide tags such that perfectly matched duplexes are formed between the tag complements and the tags of the cDNA.

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e. One of ordinary skill in the art would have been motivated to make and use microparticles having populations of a polynucleotides comprising cDNAs reverse transcribed from mRNA, because mRNA sequences are useful for the identifying and localizing genes in the genome, providing information necessary to determine the coding sequence, and analyzing cellular RNAs for activity in different tissues, stages of development, and diseases, as disclosed by Chetverin et al., at p. 13, para 2.

f. One of ordinary skill in the art would have had a reasonable expectation of success in making and using microparticles comprising populations of polynucleotides comprising cDNAs, wherein tag complements are attached to each microparticles and wherein each of said cDNA contains an oligonucleotide such that perfectly matched duplexes are formed between the tag complements and the tags of cDNAs, because the making of cDNA and microparticles that comprise oligonucleotide tags was known in the art, as taught by the aforementioned prior art.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC), Ph.D.*, whose telephone number is (703) 308-9355.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *George Elliott, Ph.D.* may be reached at (703) 308-4003.

17. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.



Mark Shibuya
April 20, 2000

DAVID GUZO
PRIMARY EXAMINER
